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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/779,457	01/07/1997	PAUL J. CARTER	P0986P2	5894

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EXAMINER
BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/10/2002

37

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/779,457	CARTER ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2002 and 21 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 22-29* is/are pending in the application.

4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 22 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *35* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

Claims1-12 and 22-29 are pending.

2. Applicant's elections of Group I, claims 1-12 and 22-29 in Paper No. 33 and a specific antibody 2D7 and specific hypervariable region of clone 3 in Paper No.36 are acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-12, 22 and 25-29 read on the elected species of a specific antibody 2D7 and specific hypervariable region of clone 3. Upon further consideration the prior art search was extended to include all specific antibody claimed in claims 10-12.

Claims 23 and 24 read on the method of identifying antibodies, wherein antibodies comprises hypervariable region of clone 4 and hypervariable region of clone 17 respectively, are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-12, 22 and 25-29 are under consideration in the instant application.

3. The specification on page 1, line 6 should be amended to reflect the status of the parent applications 08/667,197 and 08/585,005.

4. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

6. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

7. Applicant is advised that should claim 8 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite and ambiguous in the recitation of "said antibodies have biological characteristics of an antibody selected from the group… ". The metes and bounds of "biological characteristics" are unclear and indefinite.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 1-12, 22, 25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

(A). The antibodies claimed in claims 10-12 are essential to the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

It is noted that page 79 of the specification at lines 3-27 indicates that hybridomas which produce these antibodies were deposited with the ATCC under the terms of the Budapest Treaty.

If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the antibodies have been deposited under the Budapest Treaty and that the antibodies will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit, 5 years after the last request for a sample, or for the enforceable life of the patent whichever is longer. See 37 CFR 1.806.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

(B). The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112).

The attempt to incorporate subject matter into this application by reference Levin et al.,(Proc. Natl. Acad. Sci.USA 93:1726-1730, 1996) for the methods for screening for antibody which induces a statistically significant decrease in body weight and /or fat depot weight and/or food intake in an obese mammal, on page 69, lines 1-7 of the specification is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set in the MPEP 608.01(p).

(C). The specification does not provide description of the biological characteristics of 2D7 , 1G4, 1E11 and 1C11 antibodies. Thus, a person of skill in the art would not know how to use a method for identifying an antibodies, wherein said antibodies have biological characteristics of 2D7 , 1G4, 1E11 and 1C11 antibodies, encompassed by the Claims 10-12.

10. Claims 1, 3-12, 22, 25-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in obese *ob/ob* mice , does not reasonably provide enablement for a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in any obese animal including human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without any undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The instant claims are directed to a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in any obese animal including human. The data which is provided in the instant specification are based on administration of antibodies to ob/ob mice. However, one of skill in the art would not reasonably expect that a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in the ob/ob mouse to be predictive for a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in any obese animal including human. The ob/ob mouse is an animal which possesses a genetic mutation that leads to an obese phenotype that is realized at one month of age. Although the phenotype is similar in various obese animal, including human, the genetic alteration that causes the condition in mice has not been confirmed in humans in order to establish the predictability of the rodent model for humans. The working hypothesis for the ob/ob mouse is that there is a loss of a circulating satiety factor which would lead to reduction in weight and body fat if antibody to WSX or Ob/ leptin receptor are administered, and therefore, treatment of the obese. However, as no such genetic defect has been attributed to the obese condition in humans, one would not expect the same factor to be effective in humans to decrease body weight or fat-depot weight or food intake, absent evidence to the contrary. As confirmation of this scientific reasoning, researchers have found that except for the leptin-deficient obese mice (i.e. ob/ob mice), most obese mammals have elevated plasma concentrations of leptin and insulin and appear to be resistant to leptin-induced anorexia (see Woods et al. Science, 280: 1378-1383, 1998) and there is speculation that human obesity is due to reduced brain responsiveness to OB since most obese individuals have elevated serum levels of OB (see Campfield et al. Science, 280: 1383-1387, 1998). . Therefore, it is not clear that the skilled artisan could predict the efficacy of a method for identifying an antibody which decreases body weight or fat-depot weight or food intake in any obese animal including human exemplified in the specification. *In*

re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 1-12, 22 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection**.

The method for identifying an antibody which decreases a body weight or fat-depot weight or food intake in the obese animal comprising the steps claimed in Claims 1-12, 22, 25-29 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for all specific method steps and specific characteristics of antibodies claimed in claims 1-12, 22 and 25-29.

The filing date of the instant claims is the filing date of the instant applications, i.e. 01/07/1997, as the previous priority applications 08/667,197 and 08/585,005 do not support the claimed limitations of the instant application, encompassing a method for identifying an antibody recitedin claim 1-12,22 and 25-29.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 1-11 and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al. (US. Patent 5,972621).

For examination purposes it is noted that SEQ ID NO:2 of the instant application, coding human receptor variant 13.2 having a WSX motif is 100 % identical to Ob/leptin receptor (ObR) , SEQ ID NO:4 taught by Tartaglia et al.(see enclosed sequence search report).

Tartaglia et al. teach a method for identifying antibody which decrease body weight in animals, by specifically binding to extracellular domain of ObR(see entire document, Abstract , column 5, lines 44-60, column 6, lines 50-55 and column 8, lines 22-25 in particular). The method of identifying antibody comprises producing antibody, testing and identifying antibody that have an ability to decrease body weight (see column 22-23 in particular). Tartaglia et al. teach a method for identifying antibody which decrease body weight in obese animals, wherein the obese animal is *ob/ob* mice (column 2, lines 39-48 in particular). Tartaglia et al. teach a method for identifying antibody which decrease body weight in obese animals, wherein said antibody specifically bind to human receptor ObR (see column 22, lines 43-45 in particular). Tartaglia et al. teach that said antibody is monoclonal or fragment wherein said fragment is $F(ab')_2$ (column 22, lines 16-25 in particular), or human antibody, or humanized or antibody that also bind to a murine ObR receptor (column23, lines 12-24 in particular).

Claims 4-5 and 7-9 are included because both the reference method of identifying an antibody and the claimed method of identifying an antibody were using the same antigen to produced antibody therefore, the reference antibody would inherently bind to receptor having WSX motif within SEQ ID NO2 with same K_d and have the same IC50 in a KIRA ELISA.

Claims 10-12 are included because the reference antibodies that specifically binding to extracellular domain of ObR would inherently have biological characteristics of an antibodies of the instant claims.

The reference teachings anticipate the claimed invention.

13. No claim is allowed.

14. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
September 9, 2002

Christina Chan

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